

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND**

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IN RE: SMITH & NEPHEW  
BIRMINGHAM HIP RESURFACING  
(BHR) HIP IMPLANT PRODUCTS  
LIABILITY LITIGATION

MDL No. 2775  
Master Docket No. 1:17-md-2775

JUDGE CATHERINE C. BLAKE

**THIS DOCUMENT RELATES TO ALL  
THA TRACK CASES**

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**MEMORANDUM**

Pending before the court is Smith & Nephew, Inc.’s (“Smith & Nephew”) motion to amend and certify for interlocutory review the court’s order addressing dismissal of claims in the THA track. The motion has been fully briefed and oral argument was held on October 23, 2019. For the reasons set forth below, the motion will be denied.

**FACTS AND PROCEDURAL HISTORY**

Smith & Nephew seeks to appeal the court’s decision granting in part and denying in part Smith & Nephew’s motion to dismiss state law claims in two of the plaintiffs’ Master Amended Consolidated Complaints. These claims concerned two medical device “hybrid” systems: first, the use of Smith & Nephew’s Birmingham Hip Resurfacing (“BHR”) cup with Smith & Nephew’s cobalt-chrome modular femoral heads as part of total hip arthroplasties (“THA”) (referred to as the “BHR-THA” system); and second, the use of Smith & Nephew’s R3 metal liner in THA’s with a metal modular femoral head and/or with the R3 acetabular shell (referred to as the “R3-THA” system).

Smith & Nephew argued in its motion to dismiss that these claims were preempted by the Medical Device Amendments of 1976 (the “MDA”). The MDA contains an express preemption

provision, which reads “no State . . . may establish or continue in effect with respect to a device . . . any requirement which is different from, or in addition to,” any federal requirement that relates either “to the safety or effectiveness of the device” or “to any other matter” included in a federal requirement applicable to the device. 21 U.S.C. § 360k(a). The express preemption provision applies only to those devices approved through a rigorous pre-market approval (“PMA”) process. The hybrid systems at issue, though, contained both PMA-approved components and components approved through § 510(k). Section 510(k) is a more lenient approval process, and § 510(k)-approved devices are not subject to the MDA’s express preemption provision. The question, therefore, was whether state law claims directed at the hybrid systems as a whole would also be subject to the § 360k(a) preemption analysis.<sup>1</sup>

After considering the MDA, Congressional intent, and case law, the court concluded, in part, that “§ 360k(a) preempts non-parallel state law claims that target premarket-approved components, but it does not govern state-law claims that target a hybrid system’s § 510(k) components or the system as a whole.” Mem. at 15, ECF 1714. Accordingly, the court denied Smith & Nephew’s motion to dismiss certain of plaintiffs’ state law claims targeting the hybrid system as a whole. Smith & Nephew seeks to appeal this decision.

## **STANDARD OF REVIEW**

The Interlocutory Appeals Act of 1958, 28 U.S.C. § 1292(b), provides the district court with discretion to certify an interlocutory appeal of a decision not otherwise appealable. The certification of an interlocutory appeal under § 1292(b) is appropriate where a district court issues an order, and “(1) the order to be appealed involves a controlling question of law; (2) there is substantial ground for difference of opinion on that question of law; and (3) an immediate

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<sup>1</sup> More precisely, the question was whether “the federal government established requirements applicable to the specific device,” i.e. the hybrid systems. Mem. at 8, ECF 1714.

appeal from the order may materially advance the ultimate termination of the litigation.” *In re Microsoft Corp. Antitrust Litig.*, 274 F. Supp. 2d 741, 741 (D. Md. 2003) (citing 28 U.S.C. § 1292(b)).<sup>2</sup> But interlocutory appeal under § 1292(b) is the exception, not the rule. Accordingly, it “should be used sparingly” and “its requirements must be strictly construed.” *Myles v. Laffitte*, 881 F.2d 125, 127 (4th Cir. 1989). “Interlocutory appeal should not be sought to provide early review of difficult rulings in hard cases.” *Lynn v. Monarch Recovery Mgmt., Inc.*, 953 F. Supp. 2d 612, 623 (D. Md. 2013) (internal quotations and citation omitted).

## ANALYSIS

### Controlling question of law:

A question of law for the purposes of § 1292(b) is “a question of the meaning of a statutory or constitutional provision, regulation, or common law doctrine.” *Id.* (citation omitted). Therefore, § 1292(b) review may be appropriate where “the court of appeals can rule on a pure, controlling question of law” but is inappropriate where the question is one of “fact or [a] matter for the discretion of the trial court.” *United States ex rel. Michaels v. Agape Senior Comm., Inc.*, 848 F.3d 330, 341 (4th Cir. 2017) (quoting *McFarlin v. Conseco Servs., LLC*, 381 F.3d 1251, 1258–59 (11th Cir. 2004)). Section 1292(b) was not intended for questions that would require the court of appeals “to delve beyond the surface of the record in order to determine the facts.” *McFarlin*, 381 F.3d at 1259. “[C]ontrolling means serious to the conduct of the litigation, either practically or legally.” *Johnson v. Burken*, 930 F.2d 1202, 1206 (7th Cir. 1991) (internal quotation marks omitted) (quoting *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 755 (3d Cir. 1974)).

Smith & Nephew presents the controlling question of law as “Whether Plaintiffs’ claims challenging the interaction of PMA-approved BHR components with non-PMA-approved

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<sup>2</sup> A district court may amend a prior decision to state that the conditions necessary for an interlocutory appeal have been met. See Fed. R. App. P. 5(a)(3).

components as part of a ‘hybrid’ THA or R3 system are exempt from express preemption analysis under 21 U.S.C. § 360k(a).” Smith & Nephew’s Memo. in Supp. of Mot. to Amend and Certify for Interlocutory Review at 7, ECF 1722-1. As an initial matter, the court is not convinced this is a pure question of law. For example, the Third Circuit, in *Shuker v. Smith & Nephew*, looked at the specific nature of the claims made by the plaintiffs, as well as representations made at oral argument regarding how the hybrid systems were alleged to be defective, to determine whether “the heart of each of [the Shukers’] claims challenged the safety and effectiveness of the [PMA-approved] R3 metal liner.” *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 774–75 (3d Cir. 2018) (internal quotation marks omitted) (ruling on a motion for summary judgment). Likewise, in its amicus brief in *Shuker*, the Food and Drug Administration (“FDA”) also emphasized the fact-specific nature of § 360k(a), stating that “§ 360k(a) requires a court to parse a plaintiff’s claims to determine whether the state-law requirements that underlie them are indeed directed at the premarket-approved component.” FDA, Amicus Br. at 10, *Shuker*, 885 F.3d 760. Therefore, the scope of § 360k(a) as to the plaintiffs’ claims requires fact-specific inquiries.

Further, even assuming this is a pure question of law, it is not controlling. Even if the Fourth Circuit were to hold that claims targeting the hybrid system are subject to § 360k(a) analysis, a number of the plaintiffs’ claims targeting the hybrid systems, including the claims for negligent failure to warn (as to the FDA), negligent misrepresentation, fraud, fraudulent concealment, unfair & deceptive trade practice, and off-label promotion, would still go forward under the court’s analysis.<sup>3</sup> The court found that these claims were not preempted as to the

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<sup>3</sup> The *Shuker* court, on a motion to dismiss also at issue in that case, allowed the plaintiffs’ claims of off-label promotion and loss of consortium to go forward. *Shuker*, 885 F.3d at 776–78.

PMA-approved components because the state law claims were parallel<sup>4</sup> and predated the MDA.

Certain claims targeting hybrid systems, even if those systems are subject to § 360k(a), would therefore also survive preemption.

Because several of the plaintiffs' claims targeting the hybrid systems would survive regardless, it does not appear that allowing the interlocutory appeal would substantially shorten litigation. Rather, the parties will still need to conduct discovery as to the hybrid systems<sup>5</sup> and otherwise litigate these claims. Therefore, the question of the scope of §360k(a) as to hybrid systems is not serious enough to the legal or practical conduct of litigation to warrant interlocutory review.

Substantial ground for difference of opinion:

"An issue presents a substantial ground for difference of opinion if courts, as opposed to parties, disagree on a controlling legal issue." *Lynn*, 953 F. Supp. 2d at 624 (citation omitted). Substantial ground may be found when "the circuits are in dispute on the question and the court of appeals of the circuit has not spoken on the point." *Estate of Giron Alvarez v. Johns Hopkins University*, No. TDC-15-0950, 2019 WL 1779339, at \*1 (D. Md. Apr. 23, 2019).<sup>6</sup> But "[a] mere lack of unanimity, or opposing decisions outside of the governing circuit, need not persuade a court that a substantial ground for disagreement exists." *Virginia ex rel. Integra Rec, LLC v. Countrywide Sec. Corp.*, No. 3:14-cv-706, 2015 WL 3540473, at \*5 (E.D. Va. June 3, 2015).

The defendants cite to a disagreement between *Shuker* and *Lafountain v. Smith & Nephew, Inc.*, No. 14-cv-1598, 2016 WL 3919796 (D. Conn. July 18, 2016), as examples of courts disagreeing on the scope of § 360k(a) as to hybrid systems. While the court harmonized,

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<sup>4</sup> The court noted that the fraud-related claims are parallel to the extent they are based on Smith & Nephew's alleged false or misleading statements. Mem. at 24.

<sup>5</sup> As discussed *infra*, it is not likely that an immediate appeal would make discovery easier and less costly.

<sup>6</sup> Unreported decisions are cited for the soundness of their reasoning, not for any precedential value.

to some extent, the *Shuker* and *Lafountain* decisions in its Memorandum, the defendants are correct that, at least in the eyes of the *Shuker* court, their components-level approach was at odds with the approach in *Lafountain*. See *Shuker*, 885 F.3d at 775 n.14. Further, some courts have held that claims directed at hybrid systems necessarily involve claims targeting the PMA-approved component, while others have disagreed. See Mem. at 16. Therefore, there may be a lack of unanimity among courts faced with this issue, and the court will assume that there is a substantial ground for difference of opinion as to the application of § 360k(a) to hybrid systems.

Material advancement toward the ultimate termination of litigation:

“In determining whether certification will materially advance the ultimate termination of the litigation, a district court should consider whether an immediate appeal would: (1) eliminate the need for trial, (2) eliminate complex issues so as to simplify the trial, or (3) eliminate issues to make discovery easier and less costly.” *Lynn*, 953 F. Supp. 2d at 626 (internal quotations and citation omitted). “The mere fact that its resolution at this time *may* save pre-trial and trial effort and expense is not determinative; that of course can be said of any interlocutory appeal.” *Fannin v. CSX Transp., Inc.*, No. 88-8120, 1989 WL 42583, at \*5 (4th Cir. Apr. 26, 1989).

The resolution of an immediate appeal on the scope of § 360k(a) as to hybrid systems would not materially advance the ultimate termination of this litigation. As discussed earlier, it would not eliminate the need for trial. Although a resolution in Smith & Nephew’s favor may result in the dismissal of several of the plaintiffs’ claims targeting the hybrid systems, a number of claims, including nearly all of the negligence claims, would remain.

Similarly, immediate appeal would not necessarily make discovery easier and less costly. First, because several claims would survive, the plaintiffs still would be entitled to discovery (even if somewhat more limited) regarding the hybrid systems. Additionally, an immediate

appeal might even make discovery more costly, as depositions may have to be repeated if the subject areas are limited pending Fourth Circuit review, and the Fourth Circuit later denies the interlocutory appeal or agrees with this court's decision.

Further, even if the Fourth Circuit found that claims targeting the hybrid systems are subject to § 360k(a) express preemption analysis, the court may still require discovery before it can make an ultimate decision as to whether the claims are expressly preempted and should be dismissed.<sup>7</sup> See *In re Checking Account Overdraft Litigation*, No. 09-MD-02036-JLK, MDL 2036, 2010 WL 3377592, at \*2 (S.D. Fla. July 1, 2010) (“Courts require discovery and, in many cases, trial before making the ultimate determination of whether federal law preempts claims.”); FDA Amicus Br. at 12 n.4 (“The resolution of [whether §360k(a) expressly preempts a claim with respect to a combination of components including a PMA-approved component] would likely depend on fact-specific considerations, such as whether the manufacturer had marketed the components for use in combination with each other.”).

Finally, the court also notes that two cases involving similar claims targeting hybrid systems are being litigated in state court in Shelby County, Tennessee, and it appears that although Smith & Nephew raised the defense of preemption in their answers, they did not raise it in their motion to dismiss. Hr'g Tr. at 27:6–23, ECF 1898; see Smith & Nephew’s Reply at 10, ECF 1871. Therefore, it appears that the plaintiffs may alternatively<sup>8</sup> be entitled to discovery

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<sup>7</sup> Preemption analysis is not always fact-based. See Mem. (regarding the BHR track) at 10, ECF 608. In regard to the BHR-track claims, the question was whether the plaintiffs’ state law claims were parallel to federal requirements. *Id.* at 13. Here, the court must decide whether the plaintiffs’ claims targeting the hybrid systems as a whole seek to impose additional or different requirements as to PMA-approved devices, which requires a more fact-based analysis.

<sup>8</sup> At oral argument, plaintiffs’ counsel stated that Smith & Nephew did not provide discovery in the Tennessee cases because the plaintiffs were “going to get the discovery in the MDL,” but if discovery as to the hybrid systems is stayed, “we’re going to go back and say, well, now we need those in the Tennessee court cases, in the Shelby County cases . . . So the point of this is if they’re trying to avoid discovery, they have to do discovery in the Shelby County cases anyway because we’re past the Motion to Dismiss, we have a summary judgment deadline and a trial deadline, so they’re not saving anything by not doing this discovery.” Hr'g Tr. at 28:7–14, 21–25.

related to the hybrid systems in those cases, *see Hr'g Tr.* at 28:3–25, regardless of whether Smith & Nephew would be successful in their interlocutory appeal.<sup>9</sup>

## CONCLUSION

Accordingly, Smith & Nephew has not shown that the court's order on Smith & Nephew's motion to dismiss satisfies the requirements for interlocutory appeal. While the court's order may involve a question of law on which there is substantial ground for difference of opinion, the question is not controlling and its resolution would not materially advance the ultimate termination of this litigation. For the reasons set forth above, Smith & Nephew's motion will be denied. A separate order follows.

11/26/19  
Date

  
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Catherine C. Blake  
United States District Judge

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<sup>9</sup> There is some support, cited by Smith & Nephew, for the proposition that the requirements for interlocutory appeals should be construed more leniently in the MDL context. *See In re Air Crash Disaster at John F. Kennedy Int'l Airport on June 24, 1975*, 479 F. Supp. 1118, 1125 (E.D.N.Y. 1978) (“the multidistrict nature of this action clothes the liability issue with significance as a controlling question of law”); *In re Microsoft Corp. Antitrust Litigation*, 274 F. Supp. 2d at 743 (“I also consider it relevant that this is an MDL proceeding” when deciding whether to certify an order for interlocutory appeal.). Regardless of the context, though, the requirements for interlocutory appeal must be met. Those requirements, namely that there be a controlling question of law whose resolution would materially advance the ultimate termination of litigation, are not met here. *See In re Countrywide Financial Corp. Mortgage-Backed Securities Litigation*, 966 F. Supp. 2d 1031, 1046 (C.D. Cal. 2013) (“Interlocutory appeal would therefore not only fail to materially advance the litigation . . . but would interfere with the efficient coordination of cases in the [MDL].”); *In re Checking Account Overdraft Litigation*, 2010 WL 3377592 at \*3 (an interlocutory appeal in the MDL case would “not materially advance this litigation; it will delay it.”).